

Charles H. Chevalier
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
(973) 596-4611
cchevailer@gibbonslaw.com

Christine A. Gaddis
GIBBONS P.C.
141 West Front Street, Suite 240
Red Bank, New Jersey 07701
(732) 704-5801
cgaddis@gibbonslaw.com

*Attorneys for Plaintiff
American Regent, Inc.*

OF COUNSEL:

Dennies Varughese, Pharm. D.
Uma Everett
Adam LaRock
Christina Dashe
Alex Alfano
Ryan Conkin
Sterne, Kessler, Goldstein & Fox P.L.L.C.
1101 K Street, NW, 10th Floor
Washington, DC 20005
(202) 371-2600
dvarughese@sternekessler.com
ueverett@sternekessler.com
alarock@sternekessler.com
cdashe@sternekessler.com
aalfano@sternekessler.com
rconkin@sternekessler.com

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE SELENIOUS ACID LITIGATION

C.A. No. 2:24-cv-07791 (BRM) (CLW)
(Consolidated)

**PLAINTIFF'S ANSWER TO DEFENDANTS XIROMED, LLC AND XIROMED
PHARMA ESPAÑA, S.L.'S ANSWER, DEFENSES, AND
COUNTERCLAIM TO COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff/Counterclaim Defendant American Regent, Inc. (“ARI”), by its undersigned attorneys, hereby responds to the Answer, Affirmative Defenses, and Counterclaims (“Counterclaims”) of Defendants/Counterclaim Plaintiffs Xiromed, LLC and Xiromed Pharma España, S.L. (collectively, “Xiromed” or “Defendants”) (ECF No. 96) as follows:

GENERAL DENIAL

ARI denies all allegations in Xiromed’s Counterclaims except for those specifically

admitted below. With respect to the allegations made in the Counterclaims, upon knowledge with respect to ARI's own acts, and upon information and belief as to other matters, ARI responds and alleges as follows:

NATURE OF THE ACTION

1. These counterclaims include claims for a declaratory judgment of non-infringement and invalidity of U.S. Patent Nos. 12,150,957 ("the '957 patent").

ANSWER: Paragraph 1 states legal conclusions for which no response is required. To the extent a response is required, ARI admits that Xiromed purports that the Counterclaims include claims for a declaratory judgment of non-infringement and invalidity of U.S. Patent No. 12,150,957 (the "'957 patent").

THE PARTIES

2. ARI is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 5 Ramsey Road, Shirley, New York 11967.

ANSWER: Admitted.

3. Xiromed, LLC is a corporation organized and existing under the laws of the United States with its principal place of business at 180 Park Ave., Suite 101, Florham Park, New Jersey 07932.

ANSWER: On the basis of Xiromed's Answer to Paragraph 4 in the Counterclaims, admitted.

4. On information and belief, Xiromed Pharma España, S.L. is a corporation organized and existing under the laws of Spain with its principal place of business at Manuel Pombo Angulo, 28 3rd Floor, Madrid, Spain, 28050.

ANSWER: On the basis of Xiromed's Answer to Paragraph 3 in the Counterclaims, admitted.

JURISDICTION AND VENUE

5. These counterclaims arise under the patent laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

ANSWER: Paragraph 5 states legal conclusions for which no response is required. To the extent a response is required, ARI admits that Xiromed purports to bring its Counterclaims under the patent laws of the United States and 28 U.S.C §§ 2201-2202. ARI does not contest subject matter jurisdiction in this judicial district for the purposes of this action only. ARI denies that the Counterclaims have merit or that Xiromed is entitled to any relief on its Counterclaims.

6. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201.

ANSWER: Paragraph 6 states legal conclusions for which no response is required. To the extent a response is required, ARI admits that Xiromed purports to bring the Counterclaims under the patent laws of the United States and 28 U.S.C. §§ 1331, 1338(a), and 2201. ARI does not contest subject matter jurisdiction in this judicial district for the purposes of this action only. ARI denies that the Counterclaims have merit or that Xiromed is entitled to any relief on its Counterclaims.

7. Counterclaim Defendant has availed itself of this forum in this action and is therefore subject to personal jurisdiction in this Judicial District.

ANSWER: Paragraph 7 states legal conclusions for which no response is required. To the extent a response is required, ARI does not contest personal jurisdiction in this judicial district for the purposes of this action only.

8. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400, and as a result of Counterclaim Defendant's choice of forum.

ANSWER: Paragraph 8 states legal conclusions for which no response is required. To the extent a response is required, ARI does not contest venue in this judicial district for the purposes of this action only.

FIRST COUNTERCLAIM
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '957 PATENT

9. Counterclaim Plaintiffs reallege and incorporate by reference paragraphs 1 through 8 of these counterclaims as if fully set forth herein.

ANSWER: No response is required to the general re-allegation and incorporation by reference of the foregoing paragraphs of the Counterclaims. To the extent a response is required, ARI incorporates the answers in response to the foregoing paragraphs as if fully set forth herein.

10. Counterclaim Defendant has alleged in this action that Counterclaim Plaintiffs have infringed the '957 patent by filing ANDA No. 219476 seeking to obtain approval for the manufacture, use, offer for sale, sale, and/or importation of the 600 mcg/10 mL dosage strength of ARI's Selenious Acid product, as described by Counterclaim Plaintiffs in ANDA No. 219476 ("the ANDA Product") and that Counterclaim Plaintiffs' manufacture, use, offer for sale, sale in the United States, and/or importation into the United States, of the ANDA Product would infringe that patent.

ANSWER: Admitted.

11. Counterclaim Plaintiffs deny that the filing of ANDA No. 219476 was an act of infringement under 35 U.S.C. § 271 and deny that their manufacture, use, offer for sale, sale, and/or importation of the ANDA Product constitutes infringement of the '957 patent. Counterclaim Defendant's suit has improperly restrained the free exploitation of Counterclaim Plaintiffs' ANDA Product by excluding Counterclaim Plaintiffs from entering the market for the proposed drug product described in the ANDA.

ANSWER: On the basis of Xiromed's Answer to Paragraph 43 in the Counterclaims, ARI admits that Xiromed denies that the filing of ANDA No. 219476 was an act of infringement under 35 U.S.C. § 271, and that Xiromed denies that its manufacture, use, offer for sale, sale, and/or importation of the ANDA Product constitutes infringement of the '957 patent. ARI denies the remaining allegations in Paragraph 11.

12. Counterclaim Defendant's suit has improperly restrained the free exploitation of Counterclaim Plaintiffs' ANDA Product by excluding Counterclaim Plaintiffs from entering the market for the proposed drug product described in the ANDA.

ANSWER: On the basis of Xiromed's Answer to Paragraph 43 in the Counterclaims, ARI admits that Xiromed denies that the filing of ANDA No. 219476 was an act of infringement

under 35 U.S.C. § 271, and that Xiromed denies that its manufacture, use, offer for sale, sale, and/or importation of the ANDA Product constitutes infringement of the '957 patent. ARI denies the remaining allegations in Paragraph 12.

13. Counterclaim Plaintiffs have not, do not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '957 patent, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of the ANDA Product has not, does not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '957 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

ANSWER: Denied.

14. A present, genuine, and justiciable controversy exists between Counterclaim Plaintiff, on the one hand, and Counterclaim Defendants, on the other hand, regarding, *inter alia*, whether the manufacture, use, offer for sale, sale, and/or importation of a generic version of the ANDA Product infringes any valid and enforceable claim of the '957 patent.

ANSWER: Paragraph 14 states legal conclusions for which no response is required. To the extent a response is required, ARI admits there is a present, genuine, and justiciable controversy that exists between ARI and Xiromed regarding Xiromed's infringement of the '957 patent. ARI specifically denies that there is a present, genuine, and justiciable controversy that exists between ARI and Xiromed regarding invalidity of the '957 patent.

15. Counterclaim Plaintiffs are entitled to a declaration by this Court that one or more claims of the '957 patent are not infringed.

ANSWER: Denied.

16. Counterclaim Plaintiffs are entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

ANSWER: Denied.

SECOND COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY OF THE '957 PATENT

17. Counterclaim Plaintiffs repeat and incorporate by reference each of the foregoing paragraphs 1–15 of its Counterclaims.

ANSWER: No response is required to the general re-allegation and incorporation by reference of the foregoing paragraphs of the Counterclaims. To the extent a response is required, ARI incorporates the answers in response to the foregoing paragraphs as if fully set forth herein.

18. Counterclaim Defendant has accused Counterclaim Plaintiffs of infringing claims of the '957 patent in connection with ANDA No. 219476.

ANSWER: Admitted.

19. Counterclaim Plaintiffs deny infringement of any claim of the '957 patent because all claims of the '957 patent are invalid for failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code. Given their invalidity, Counterclaim Plaintiffs cannot infringe the claims of the '957 patent, including for at least the reasons set forth in the detailed statements included with Counterclaim Plaintiffs' Notice Letter.

ANSWER: On the basis of Xiromed's Third Separate Defense in the Counterclaims and Notice Letter, ARI admits that Xiromed denies infringement of any claim of the '957 patent because all claims of the '957 patent are allegedly invalid for failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code. ARI denies the remaining allegations in Paragraph 19.

20. The alleged inventions of the '957 patent lack written description support and do no more than combine familiar elements through known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '957 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged inventions of the '957 patent and would have had a reasonable expectation of success in doing so.

ANSWER: Denied.

21. The claims of the '957 patent are invalid at least under 35 U.S.C. §§ 102, 103, and/or 112.

ANSWER: Denied.

22. Unless Counterclaim Defendant is enjoined, Counterclaim Plaintiffs believe that Counterclaim Defendant will continue to assert that Counterclaim Plaintiffs infringe the claims of the '957 patent and will continue to interfere with Counterclaim Plaintiffs' business.

ANSWER: Denied.

23. Counterclaim Plaintiffs will be irreparably harmed if Counterclaim Defendant is not enjoined from continuing to assert the claims of the '957 patent and from interfering with Counterclaim Plaintiffs' business.

ANSWER: Denied.

24. A definite and concrete, real and substantial, justiciable controversy exists between Counterclaim Plaintiffs and Counterclaim Defendant concerning the invalidity of the claims of the '957 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ANSWER: Paragraph 24 states legal conclusions for which no response is required. To the extent a response is required, ARI admits a definite and concrete, real and substantial, justiciable controversy exists between ARI and Xiromed regarding Xiromed's infringement of the '957 patent. ARI specifically denies a definite and concrete, real and substantial, justiciable controversy exists between ARI and Xiromed regarding invalidity of the '957 patent.

25. Counterclaim Plaintiffs are entitled to a declaratory judgment that the asserted claims of the '957 patent are invalid.

ANSWER: Denied.

EXCEPTIONAL CASE

26. This case is an exceptional one and Counterclaim Plaintiffs are entitled to an award of their reasonable attorneys' fees and costs under 35 U.S.C. § 285.

ANSWER: Denied.

PRAYER FOR RELIEF

ARI denies that Xiromed is entitled to any judgment or relief against ARI and, therefore specifically denies Paragraphs (a)–(c) of Counterclaimant Xiromed's Prayer for Relief.

Each averment and/or allegation contained in Xiromed's Counterclaims that is not specifically admitted herein is hereby denied.

ARI requests that judgment be entered in its favor, dismissing Xiromed's Counterclaims with prejudice, awarding ARI's attorneys' fees and costs incurred in this litigation under 35 U.S.C.

§ 285, and granting even further relief as the Court may deem just and proper.

Dated: January 28, 2025

By: s/ Charles H. Chevalier
Charles H. Chevalier
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
(973) 596-4611
cchevalier@gibbonslaw.com

Christine A. Gaddis
GIBBONS P.C.
141 West Front Street, Suite 240
Red Bank, New Jersey 07701
(732) 704-5801
cgaddis@gibbonslaw.com

OF COUNSEL:

Dennies Varughese, Pharm. D.
Uma Everett
Adam LaRock
Christina Dashe
Alex Alfano
Ryan Conkin
Sterne, Kessler, Goldstein & Fox P.L.L.C.
1101 K Street, NW, 10th Floor
Washington, DC 20005
(202) 371-2600
dvarughese@sternekessler.com
ueverett@sternekessler.com
alarock@sternekessler.com
cdashe@sternekessler.com
aalfano@sternekessler.com
rconkin@sternekessler.com

*Attorneys for Plaintiff
American Regent, Inc.*

CERTIFICATE OF SERVICE

I hereby certify that on January 28, 2025, a true and correct copy of Plaintiff's Answer to Defendant's Answer, Defenses, and Counterclaim to Complaint for Patent Infringement was served by ECF on all counsel of record and electronic mail on all counsel of record for Xiromed.

Date: January 28, 2025

s/ Charles H. Chevalier

Charles H. Chevalier